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A RANDOMIZED, DOUBLE BLIND, PLACEBO CONTROLLED STUDY FOR EVALUATING EFFICACY AND SAFETY OF NUTRICHARGE BJ FOR KNEE JOINT PAIN IN HEALTHY ELDERLY POPULATION.

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Abstract:

The elderly patients suffering from knee related problems should know the importance of usage of nutrient supplements and also selfcare activities which are inexpensive and at the same time are useful in overcoming the problems, especially pain. The study was aimed for determining the efficacy and safety of one such supplement namely Nutricharge BJ for regaining the knee joint health in the elderly population. The study was designed as a single centre, randomized, double blind, placebo controlled trial to evaluate the efficacy and safety. The study subjects had undergone physical findings on examination of the knee, Short-Form McGill Pain Questionnaire-2 (SF-MPQ-2), Pain Visual Analog Scale, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and pain scale and self-assessment questionnaire both before and after a treatment period for assessing the safety and efficacy of Nutricharge BJ. It was observed that a reduction of 57.5% in SF-MPQ2 pain scores occurred in the Nutricharge BJ Group and was highly statistically significant. TheWOMAC scores in the Nutricharge BJ group, when compared to placebo Group were found to be 73.7%. It was found that the difference in reduction in WOMAC pain scores between the two groups over a period of the 90-days was highly significant (P<0.0001).The Pain Scale function scores before and after the period of follow-up showed significant reduction in pain (87.3%) between the two groups.In pain visual analogue scale and patient assessment questionnaire, a reduction of 53.6% and 54.1% was observed respectively in Nutricharge BJ group and was significant. The Nutricharge BJ supplement significantly aids in improving the physical function, activity and above all the quality of life in the elderly population. It was observed that there was no adverse drug reactions were reported during the study period and thus showing the product-Nutricharge BJ is safe for human consumption.

Keywords:Knee Joint, WOMAC™, Nutrition Supplement, BUA

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INTRODUCTION:

Nutrients and dietary supplements have been shown to be effective at relieving the symptoms of OA, and some may have a role in influencing the course of OA . There is growing recognition of the importance of nutritional factors in the maintenance of bone and joint health .

Reactive oxygen species, which are generated by cells within joints and cause oxidative damage to various macromolecules, have been shown to play a role in the pathogenesis of OA . Vitamin C, vitamin E, and carotenoids are excellent antioxidants that protect cells from damage by oxidants, and whose blood concentrations are primarily determined by dietary intake . These antioxidants may have a beneficial effect on joint health. The Framingham OA Cohort Study suggested that dietary vitamin C, vitamin E, and β-carotene reduced the risk of progression of knee OA .

Osteoarthritis (OA) is the most common type of arthritis or degenerative joint disease (1) in elderly patients. It is a leading cause of chronic disability for patients aged more than 45 years. The disease most commonly affects the middle-aged and elderly, although younger people may be affected as a result of injury or overuse. Age is the strongest predictor of the disease and therefore increasing age and extended life expectancy will result in a greater occurrence of the disease. It is a common chronic, progressive musculoskeletal disorder characterized by gradual loss of articular cartilage.

Despite intense epidemiologic studies, the exact prevalence of joint pains is unknown, owing to the uncertainties and variations of diagnostic definition and reported mechanisms. Another outcome is that many patients with radiographically apparent OA do not have symptoms that lead them to medical care. Based on the prevalence data from the National Centre for Health Statistics an estimated number of 15.8 million adultsor 12% of those between 25 and 74 years of age have signs and symptoms of OA(2).

Although the risk factors associated with knee joint pains have been well documented but the pathophysiology of the joints resulting in the clinical signs and symptoms is still not clearly understood. They can affect any of the synovial joints but it occurs commonly in hand, knee, and hip joints (3).It is characterized by the degeneration of a synovial joint resulting from the progressive loss in articular cartilage and abnormal remodeling of the subarticular bone and the formation of bone cysts and osteophytes(3, 4). Primarily OA is referred to as such when the cause of joint degeneration is not known. It is rarely diagnosed in patients below 40 years of age.On the other handthe secondary arthritisis the development of disease after trauma or injury to the affected joint, or the result of a preexisting hereditary, inflammatory, developmental, metabolic, or neurologic disorder(5).OA of the knee is often associated with pain in and around the joint, stiffness, crepitation, and limited joint motion (6). The progression of OA disease is slow and treatment of OA includes exercise, heat or cold therapy, joint protection, weight loss, physiotherapy/occupational therapy, and of course medication (7). Relieving or improving joint pain and stiffness and overall physical function are current recommendations for the management of therapy (8, 9).

The most common medications for OA include acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs) such as cyclo-oxygenase II (COX-2) inhibitors. These medications are effective in reducing pain associated with OA but do not prevent disease progression. Additionally, there are many serious potential side-effects associated with NSAIDs, including upper gastrointestinal tract problems, hypertension, congestive heart failure, and renal insufficiency (10, 11).

Complementary and alternative medicines (CAMs) are being increasingly sought after by consumers to alleviate OA-associated pain. Althoughknee joint painis no longer considered to be anormal part of aging process, growingoldercontinuestobethemostconsistentlyidentifiedriskfactorfordisease development.Keeping bones and joints healthy becomes extra important with progression of age. Seriousconditions such as arthritis and knee joint pain can make it tough to move around and maylead to even more medical complications.

It is proved that diet can play a significant role in preventing bone and jointdiseases. Bone & Joints health is the result of bone mass, bone architecture, and bodymechanics—all of which are dependent on nutrition all through the human life cycle. Bone & Joints health is a multi-factorial musculoskeletal issue (12). Bone Mineral Density (BMD) and bone metabolism are affected by genetic, endocrine, mechanical, andnutritional factors, with extensive interactions between the different factors (13, 14). Thoughthe effects of dietary intake on bone metabolism have received negligible attention in theliterature (15) but, many investigations have strongly suggested a key role for foodsupplements and nutrients in safeguarding the health of bone and joints (16-19). The management strategies of patients also need to be regularly reviewed and adjusted in light of their response and adherence. This will vary between patients and location.The management of pain is broadly divided into non-pharmacological, pharmacological, and surgical treatments.

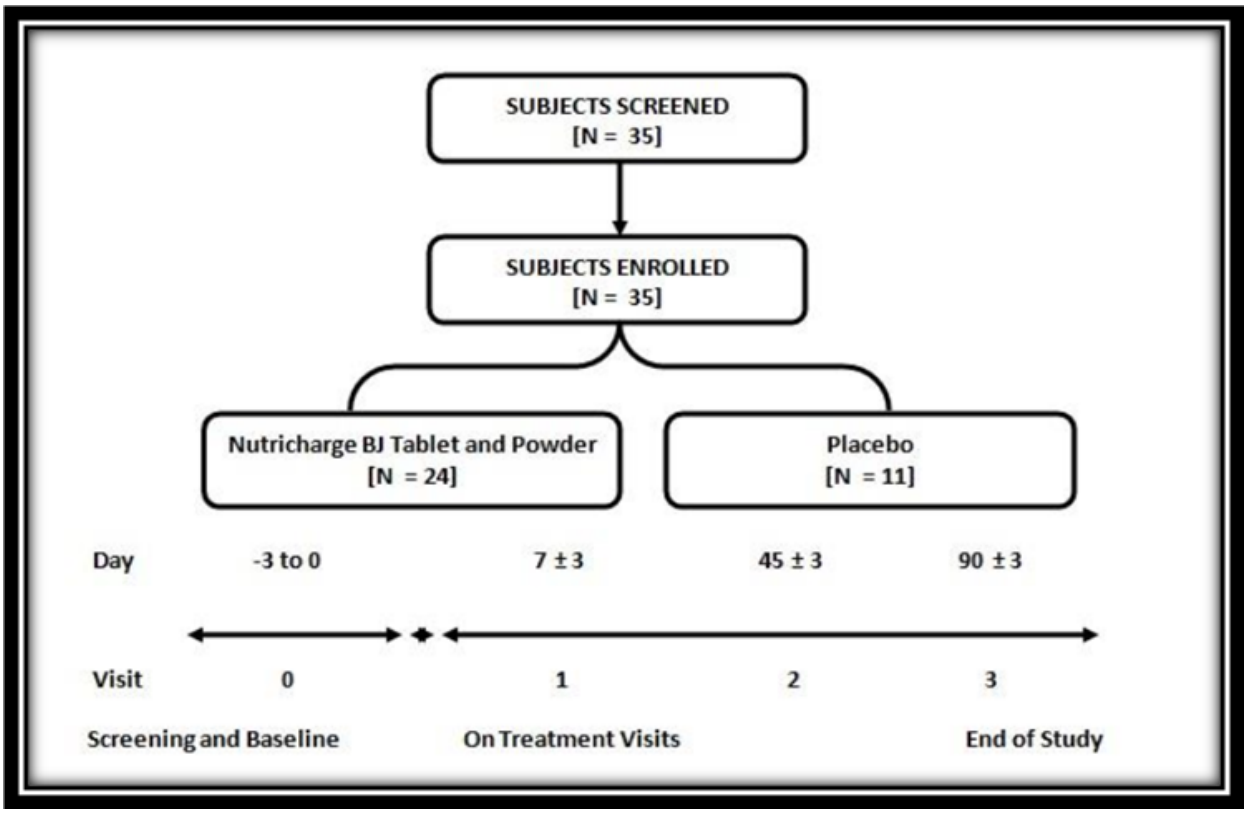

Fig 1: Study Design and Plan of the distribution of supplement and placebo.

Surgical treatment is generally reserved for failed medical management with functional disability affecting a patient's quality of life. Hence there is a need of complimentary treatment which can overcome the side effects and improve the overall quality of human life.

MATERIALS AND METHODS:

This study was performed to assist the Sponsor ingathering information about the efficacy and safety of Nutricharge BJ for bone health in elderly population.This is a single centre, randomized, double blind, placebo controlled trial toevaluate the efficacy and safety. The subjects will undergo Physical findings on examination of theknee, Short-Form McGill Pain Questionnaire-2 (SF-MPQ-2), Pain Visual Analog Scale,Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and self-assessment questionnaire both before and after a treatment period forassessing efficacy and safety of Nutricharge BJ.

During first visit the subjects were underwent an evaluation for determining the eligibility based on the investigator assessment. During the Visit 0for allsubjects, informed consent was obtained with demographics and medical history. Subjects were examined for physical and systemic examination for evaluating the health status of subject's participating in the trial.

A total of 35 male and female subjects aged on 45 to 65 years, who satisfied the inclusioncriteriawere enrolled in the study. Physical findings on examination of theknee (Limping gait, Weight bearing, Swelling, Bruising, Atrophy and Alignment) by theprincipal Investigator were collected from all subjects before the treatment. SF-MPQ-2,Pain Visual Analog Scale, WOMAC and Pain score of the knee were also collected fromall subjects by using pain scale. During the end of Visit 0 the eligible subjects were assigned to either of the treatment groupsin 2:1 ratio as per randomization. One group received Nutricharge BJand another group received placebo.The subjects were instructed to take one nutritional sachet and one nutritional tablettogether and placebo in the morning with milk. The same treatment wasgiven for period of 90 Days.During the second and third visit the subject kneepain evaluations and self-assessment questionnairewere recorded. On the concluding visit of 90 days, subjects were examined for various measurements along with knee pain evaluations and self-assessment questionnaire.

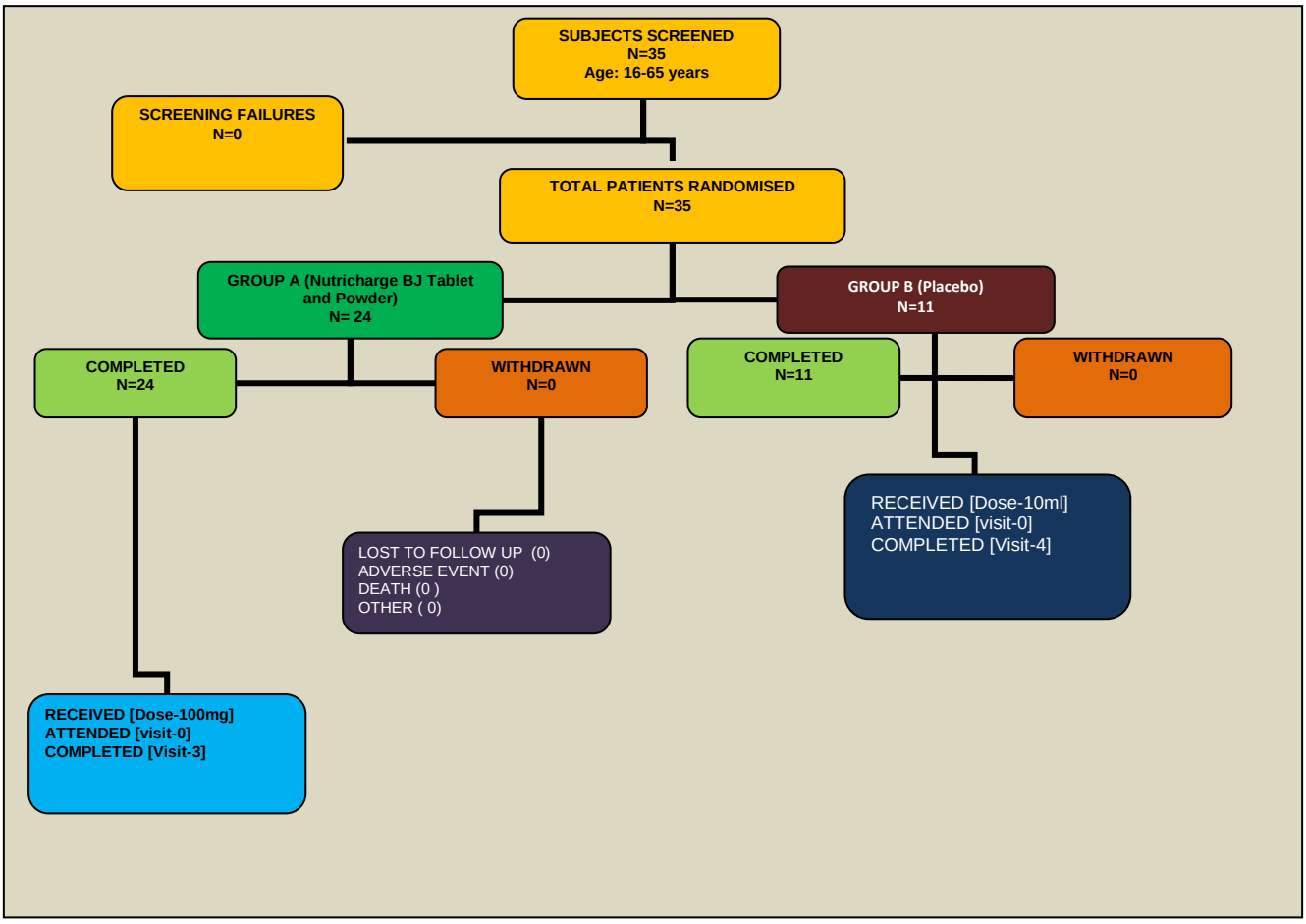

Fig 2: Flow diagram of the disposition of subjects screened and enrolled into the study.

Subjects were required to meet all of the following inclusion criteria to be eligible for inclusion in thestudy: such as subjects aged between 45 and 65 years with normal outcome of the Medical and Surgical history. The subjects were able to communicate effectively and adhere to the protocol requirements. The subjects with contraindications or Hypersensitivity to investigational drug and related herbalproducts were excluded from the study. History or presences of any medical condition were also excluded from the study. Subjects participating in any other trial and female subjects with pregnancy or doing breast feeding were not included in the study.The subjects were randomly allocated to the test and control drugs in the ratio of 2:1. In testgroup a total of 24 subjects received Nutricharge BJ, while in control group 11 subjects received the Placebo.The subjects were instructed to take single nutritional sachet and one nutritionaltablet together and matching placeboonce in a day in the morning along withmilk. Thesame procedure for the treatment was given for 90 days.Treatment compliance was assessed on the basis of subject diary cards by using the following formula

$$\frac{\text{Number of doses administered) x 100}}{\text{Number of doses to be administered till visit}}$$

Subjects compliance were calculated based on the approximately of 80% to 125% ofthe doses of the study drug and the evaluations werecompleted within thedesignated visit.

Two ultra sound variables viz., BUA (*Broadband Ultrasound Attenuation) and SOS (Speed of Sound)* were evaluated. A third variable Stiffness Index was calculated based upon the BUA and SOS values as follows:

Stiffness Index = [0.67 * (BUA) + 0.28 * (SOS)-420]

BMD (Bone Mass Density) was assessed using ultrasound densitometer in the oscalcis of right foot. The results were analyzed and interpreted in terms of T & Z Scores following WHO recommended scales as defined below. T-score compares your bone density with that of healthy young women.Z-score

compares your bone density with that of other people of your age, gender, and race.

Interpretation of Scores:

- A T-score of -1.0 or above is considered a normal bone density. Examples are 0.9, 0 and -0.9.
- A T-score between -1.0 and -2.5 means you have a low bone density or osteopenia. Examples are T-scores of -1.1, -1.6 and -2.4.
- A T-score of -2.5 or below is a diagnosis of osteoporosis. Examples are T-scores of -2.6, -3.3 and -3.9.
- A Z-score above -2.0 is normal according to the International Society for Clinical Densitometry (ISCD).

STATISTICAL ANALYSIS:

The data values are expressed in terms of Mean and Standard Deviation. The significant levels of ($p<0.05$) points using unpaired t-test were used for evaluation. The Bone Density or Bone Mineral Density was evaluated using T-Score and Z-Score as per WHO recommendations. The descriptivestatistics for continuous variables were presented with number (n) of non-missing observations, Mean, Standard Deviation (SD), Minimum and Maximum. Forcategorical data, descriptive statistics were presented with number (n) and theirpercentages

RESULTS:

The mean age for the treatment group was 37.6 years and corresponding placebo group was 37.5 years. The distribution of female and male subjects in the treatment group was 78.3% and in the placebo group was 21.7%. The detailed demographic characteristics between the two groups are represented in theFigure-3.

SF-MPQ2 mean pain scores of the Nutricharge BJ treatment group at the baseline and 4th visit were 4.0 and 1.8 respectively. The change from the baselinemean scores was found to be 2.3. Whereas in the placebo group the corresponding base line and visit 4 mean scores were recorded as 4.1for both the visits and difference of the mean scores was found to be zero. The results were clearly depicted in Table 1 and Figure 4.During the completion period of 90 days there was no reduction in baseline scores of SF-MPQ2 in the placebo group when compared to Nutricharge BJ Group (57.5%). The difference in reduction in SF-MPQ2 pain scores between the two groups over the 90-day study period was highly statistically significant ($P<0.0001$).

The pain visual analogue scale mean score for the Nutricharge treatment group at the baseline and 4thvisit were 2.8 and 1.3 respectively. The variation from the mean scores was found to be 1.5. Whereas in the placebo group the corresponding base line and visit 4 mean scores werefound to be 2.6 for both the visit and difference was zero (Table 2 and Figure 5). There was no reduction in baseline Pain VisualAnalogue Scale scores in the placebo group when compared to Nutricharge BJ Group (53.6%) during the end of the 90 days period. The difference in reduction in Pain Visual Analogue Scale painscores between the two groups over the 90-day study period was highly statisticallysignificant ($P<0.0001$).

WOMAC mean pain score for the Nutricharge treatment group at the baseline and 4th visit were found to be 46.0 and 12.1 respectively. The difference in the mean scores was found to be 33.9. In the placebo group both the corresponding base line and visit 4th mean scores was recorded as 39.9 for both the visits and difference in the mean scores was zero. The results were tabulated in Table 3 and Figure 6.It was observed that there was no reduction in baseline WOMAC scores in the placebo groupcompared to 73.7% reduction in the Nutricharge BJ treatment group. The difference in reduction in WOMAC pain scores between the two groups over the 90-day study period was highly statistically significant ($P<0.0001$).

Pain Scale mean pain scores for the Nutricharge treatment group at the baseline and 4thvisit were 21.2 and 2.7 respectively and the difference of the mean scores from the baseline was found to be 18.5. In the Placebo group both the corresponding base line and visit 4 mean scores were recorded as 17.0 for both the visits and difference of the mean scores was zero. The results were tabulated in Table 4 and Figure 7.During the completion of 90 days of treatment period there was no reduction in baseline Pain Scale scores in the placebo group. Whereas in the Nutricharge BJ Groupit was found to be 87.3%. The difference in reduction in Pain Scale pain scores between the two groups over the 90day study period was highly statistically significant ($P<0.0001$).

The mean post trialassessment pain score for the Nutricharge treatment group at the baseline visit and 4th visit were found to be 19.4 and 8.9. The difference to that of baseline was found to be 10.5. In the Placebo group the corresponding base line and visit 4 mean scores was found to be 18.3 for both the visits and difference of the mean scores was zero. The results were tabulated in Table 5 and Figure 8.During the end of treatment period of 90 days it was observed that there was no reduction in baseline PTAssessment scores in the placebo group. Where as in the Nutricharge group BJthere was a 54.1% reduction in assessment scores. The difference in reduction in Pain Scale pain scores between the two

groups was highly statistically significant (*P*<0.0001).

The mean Stiffness Index in the treatment group was reported as 88.3 at base line and increased to 89.1 at visit4 and correspondingly in placebo group it was found to be87.4 and 89.2 mean values respectively.The incremental difference of change in means values for baseline and visit 4 in the two treatment groups (Nutricharge BJ and Placebo) were 1.5 and 1.8. There is no statistical significant difference in the mean values of Stiffness Index between Nutricharge BJ and Placebo groups (*P=0.9075*) (Table 6 and Figure 9).

The mean BUA in the treatment group was reported as 108.5 at base line and decreased to 108.1 during 4thvisit and correspondingly in placebo group the baseline and visit 4 the mean values were 107.0 and 105.8 respectively.The reduction in means values for baseline and visit 4 in the two treatment groups (Nutricharge BJ and Placebo) were 0.3 and 1.1 respectively. It was found that there was no statistically significant difference in the mean values of BUA between Nutricharge BJ and Placebo groups (*P=0.6772*). (Table 7 and Figure 10)

The mean speed of sound in the treatment group was reported as 1558.9 at baseline and increased to 1564.3 at the 4th visit and correspondingly in Placebo group the baseline and visit 4 the mean values were 1558.1 and 1566.5 respectively.The difference in mean values for baseline and visit 4 in the two treatment groups (Nutricharge BJ and Placebo) were 6.4 and 8.5 respectively. There was no statistical significance between Nutricharge BJ and Placebo groups (*P=0.7645*).(Table 8 and Figure 11).

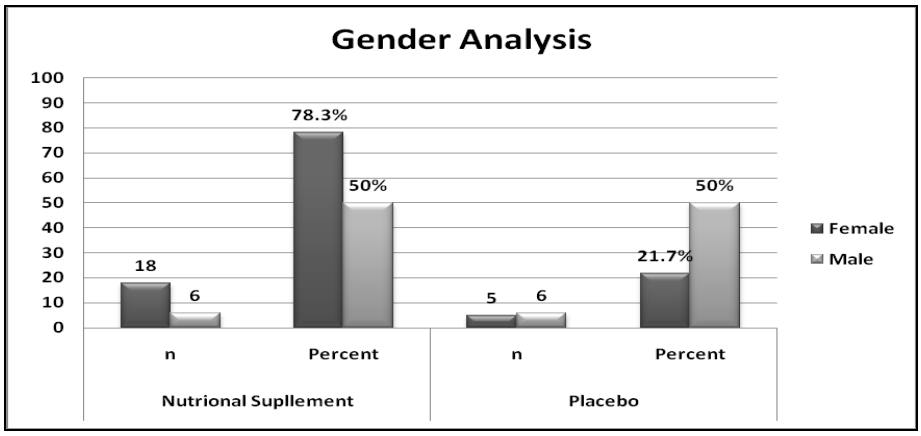

Fig 3: Demographic report of the study subjects.

Table 1: Data Analysis shows the general statistics mean and standard deviation forscores derived based on SF-MPQ2 Method at baseline, IV visit and change frombaseline.

Variable/SF-MPQ2	Nutritional Supplement (N=24)		Placebo (N=11)		*p*-Value
	MEAN	STD	MEAN	STD	
Baseline	4.0	0.3	4.1	0.0	0.2808
Visit IV	1.8	0.5	4.1	0.0	<0.0001
Change from Baseline	-2.3	0.4	0.0	0.0	<0.0001
% Change from baseline	-57.5	-	0.0	-	-

***** *N= Number of Subjects allotted to each treatment group;*
Mean=Arithmetic Mean; STD=Standard Deviation;

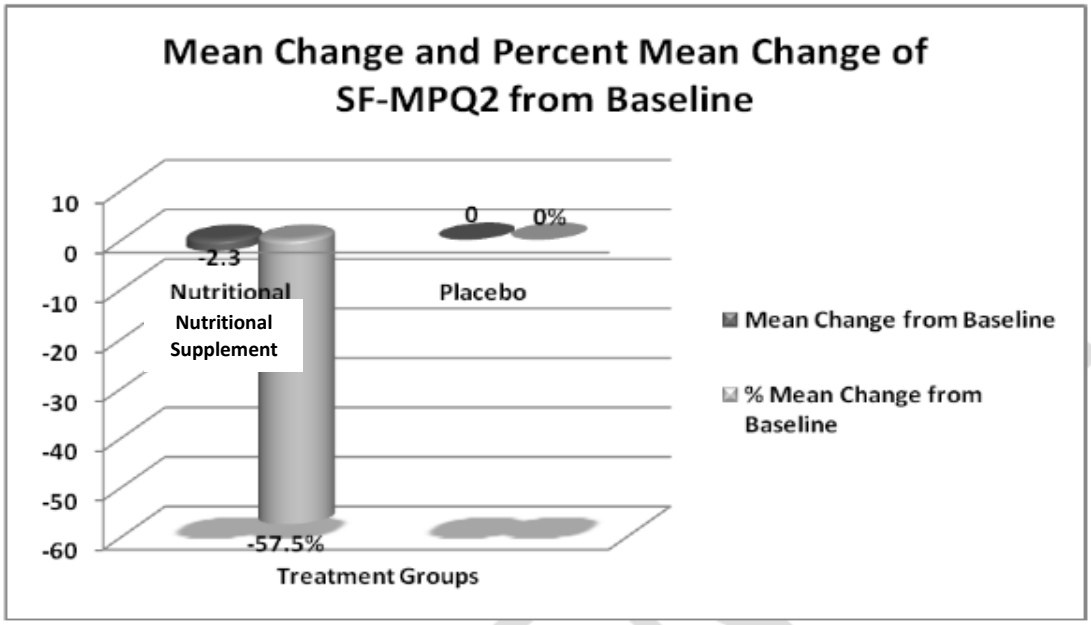

Fig 4: Graphical representation of the analyzed data on SF-MPQ2 from baseline.

Table 2: Interpretation of the Analysis on Pain Visual Analogue Scale.

Variable/Pain Visual Analogue Scale	Nutritional Supplement (Nutricharge BJ) (N=24)		Placebo (N=11)		*P*-Value
	MEAN	STD	MEAN	STD	
Baseline	2.8	0.4	2.6	0.5	0.2132
Visit IV	1.3	0.5	2.6	0.5	<0.0001
Change from Baseline	-1.5	0.5	0.0	0.0	<0.0001
% Change from baseline	-53.6	-	0.0	-	-

***** *N= Number of Subjects allotted to each treatment group;*
Mean=Arithmetic Mean; STD=Standard Deviation;

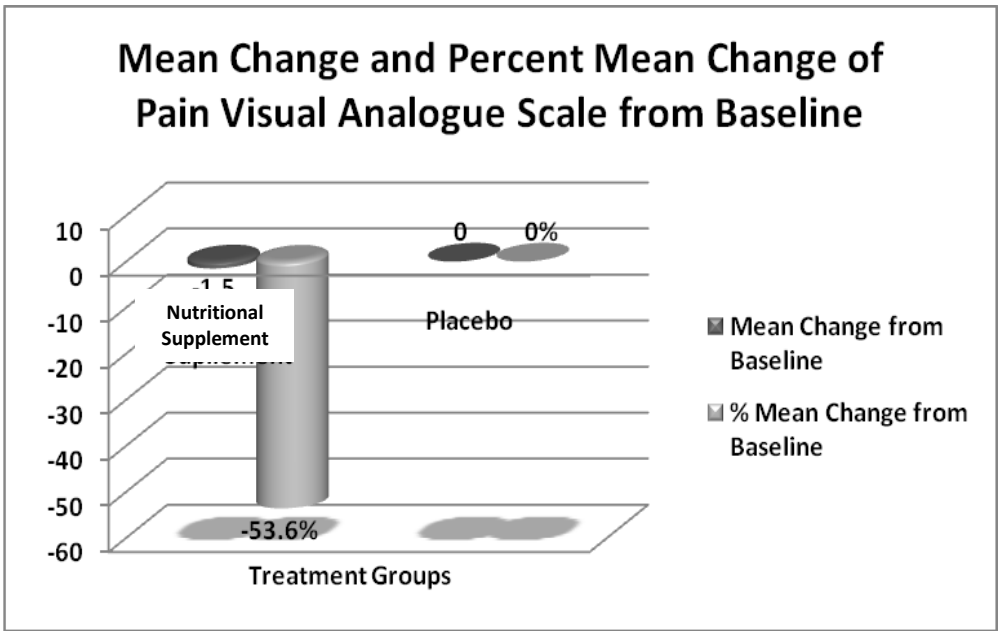

Fig 5: Graphical representation of the analyzed data on Pain Visual Analogue Scale.

Table 3: Analysis performed on the Nutricharge BJ to that of placebo on WOMAC index

Variable/ WOMAC	Nutritional Supplement (Nutricharge BJ) (N=24)		Placebo (N=11)		*P*-Value
	MEAN	STD	MEAN	STD	
Baseline	46.0	8.7	39.9	13.7	0.1191
Visit IV	12.1	4.4	39.9	13.7	<0.0001
Change from Baseline	-33.9	6.3	0.0	0.0	<0.0001
% Change from baseline	-73.7%	-	0.0	-	-

***** *N= Number of Subjects allotted to each treatment group*
Mean=Arithmetic Mean; STD=Standard Deviation;

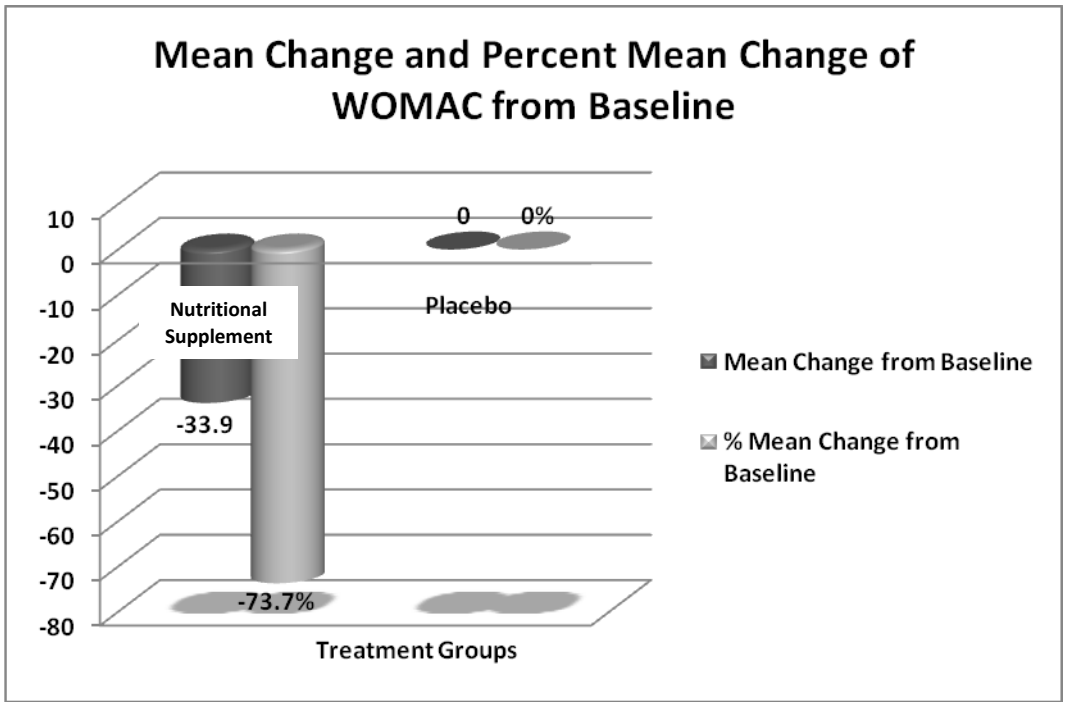

Fig 6: Graphical Representation of WOMAC index in both Nutricharge BJ and placebo treated subjects

Table 4:The general statistics for Pain Scale in mean and standard deviation forscores derived based on Pain Scale Method at baseline

Variable/Pain Scale	Nutritional Supplement (Nutricharge BJ) (N=24)		Placebo (N=11)		*P*-Value
	MEAN	STD	MEAN	STD	
Baseline	21.2	4.7	17.0	5.6	0.0272
Visit IV	2.7	1.1	17.0	5.6	<0.0001
Change from Baseline	-18.5	3.9	0.0	0.0	<0.0001
% Change from baseline	-87.3	-	0.0	-	-

***** *N= Number of Subjects allotted to each treatment group;*
Mean=Arithmetic Mean; STD=Standard Deviation;

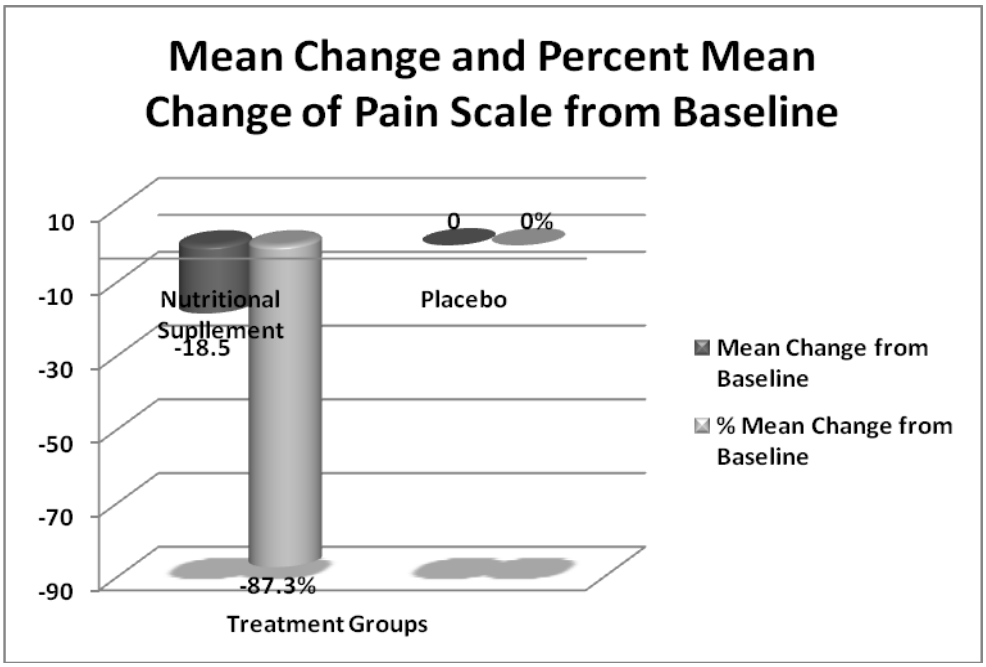

Fig 7: Graphical Representation of mean percent change in the Pain Scale

Table 5: Assessment of PT in both the treated groups of nutricharge and placebo

Variable/Pt Assessment	Nutritional Supplement (Nutricharge BJ) (N=24)		Placebo (N=11)		*P*-Value
	MEAN	STD	MEAN	STD	
Baseline	19.4	3.3	18.3	2.9	0.3496
Visit IV	8.9	1.0	18.3	2.9	<0.0001
Change from Baseline	-10.5	2.9	0.0	0.0	<0.0001
% Change from baseline	-54.1	-	0.0	-	-

***** *N= Number of Subjects allotted to each treatment group;*
Mean=Arithmetic Mean; STD=Standard Deviation;

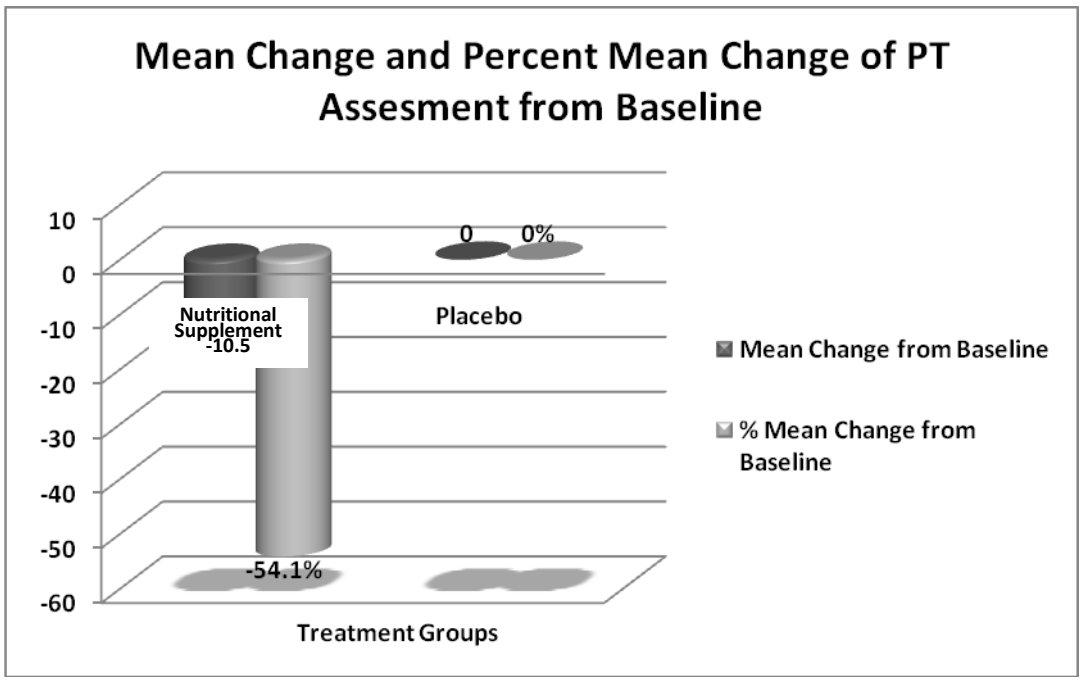

Fig 8: Graphical representation of percent mean change in PT Assessment

Table 6: Evaluation of Stiffness Indices of Nutricharge BJ and its comparison with placebo

Variable/ Stiffness Index	Nutritional Supplement (Nutricharge BJ) (N=24)		Placebo (N=11)		*P*-Value
	MEAN	STD	MEAN	STD	
Baseline	88.3	15.8	87.4	12.1	0.8682
Visit IV	89.1	13.3	89.2	13.7	0.9838
Change from Baseline	1.5	7.1	1.8	6.9	0.9075
% Change from baseline	1.7	-	2.1	-	-

***** *N= Number of Subjects allotted to each treatment group;*
Mean=Arithmetic Mean; STD=Standard Deviation;

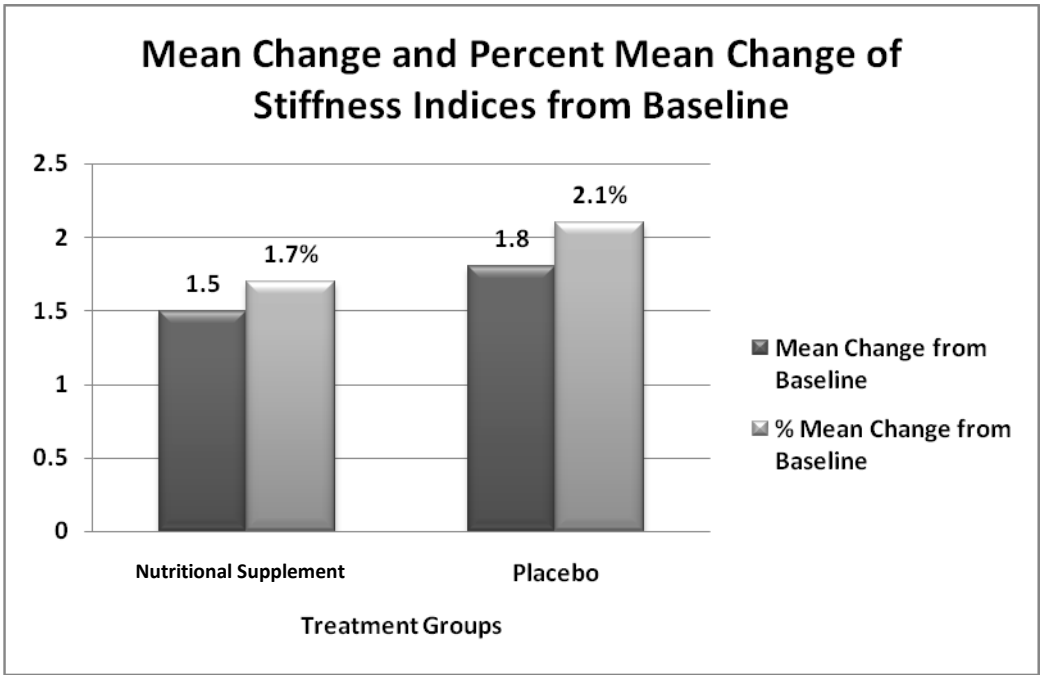

Fig 9: Graphical representation of Stiffness Indices in terms of percent means change from baseline.

Table 7: Analysis of Broadband Ultrasound Attenuation (BUA) test Method of Nutricharge BJ in comparison with placebo.

Variable/BUA	Nutritional Supplement (Nutricharge BJ) (N=24)		Placebo (N=11)		*P*-Value
	MEAN	STD	MEAN	STD	
Baseline	108.5	12.2	107.0	7.1	0.7081
Visit IV	108.1	10.1	105.8	7.6	0.5068
Change from Baseline	-0.3	6.3	-1.2	4.8	0.6772
% Change from baseline	-0.3	-	-1.1	-	

***** *N= Number of Subjects allotted to each treatment group;*
Mean=Arithmetic Mean; STD=Standard Deviation;

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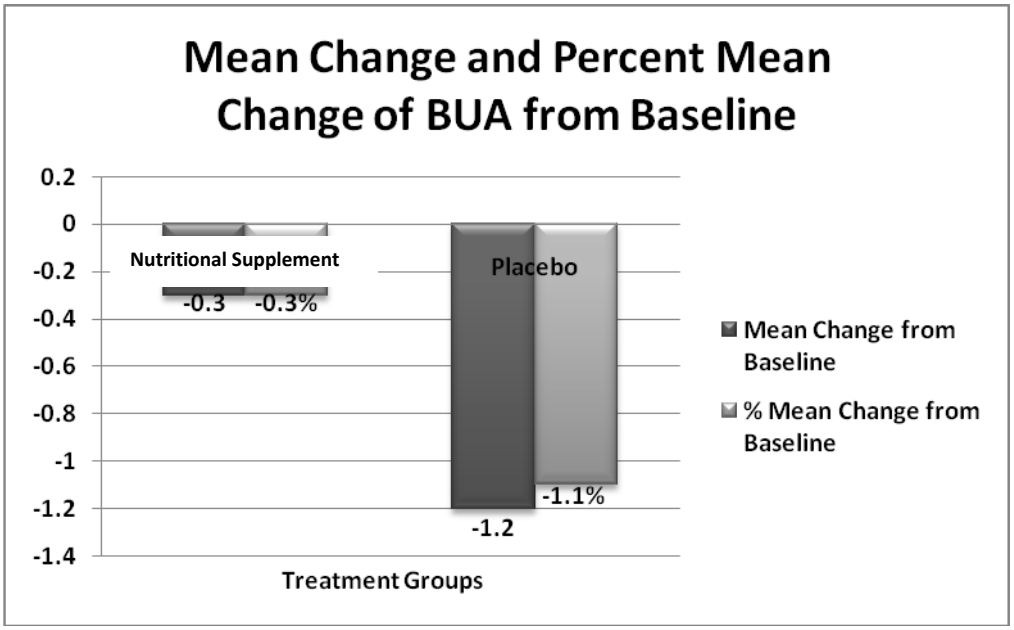

Fig 10: Graphical representation of percent means change in BUA from baseline

Table 8: Analysis of Speed of Sound/Velocity (SOS) tests Methodof Nutricharge BJ supplement in comparison with placebo.

Variable/SOS	Nutritional Supplement (Nutricharge BJ) (N=24)		Placebo (N=11)		*P*-Value
	MEAN	STD	MEAN	STD	
Baseline	1558.9	31.6	1558.1	30.9	0.9446
Visit IV	1564.3	30.2	1566.5	33.9	0.8484
Change from Baseline	6.4	19.9	8.5	17.1	0.7645
% Change from baseline	0.4	-	0.5	-	

***** *N= Number of Subjects allotted to each treatment group; Mean=Arithmetic Mean; STD=Standard Deviation;*

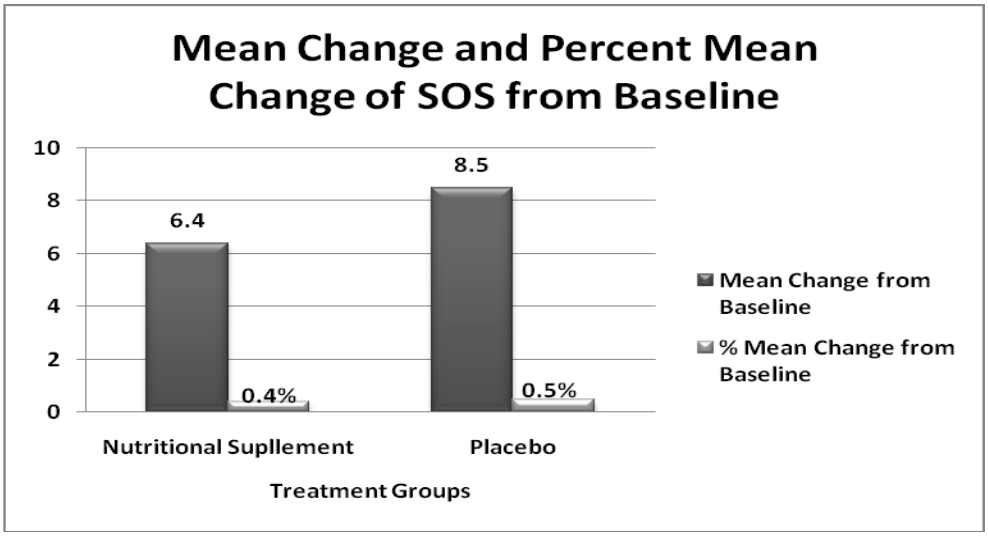

Fig 11: Graphical representations of percent mean change in SOS from baseline

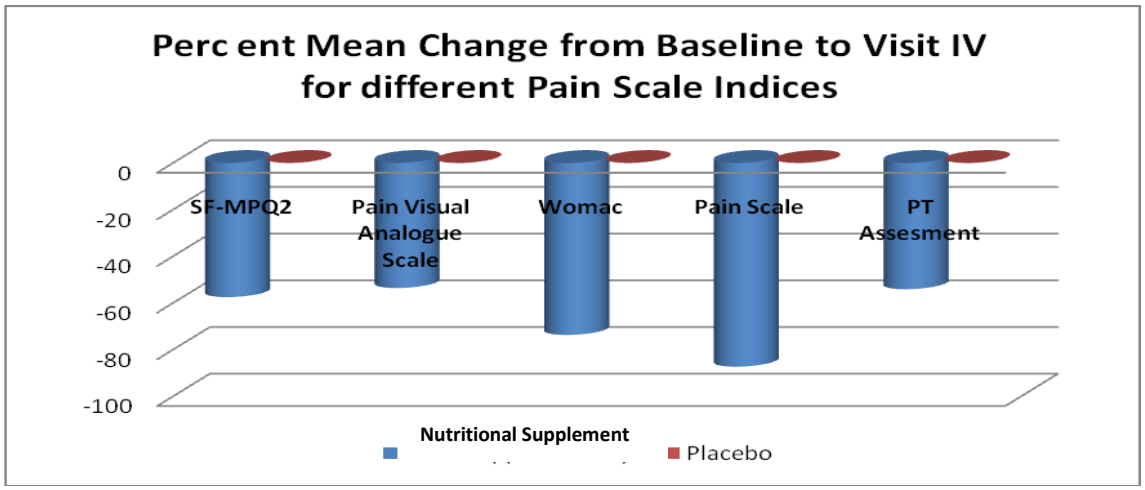

Fig 12: Percent Mean Changes from Baseline to Visit IV for different Pain Scale Indices shows in one Graph.

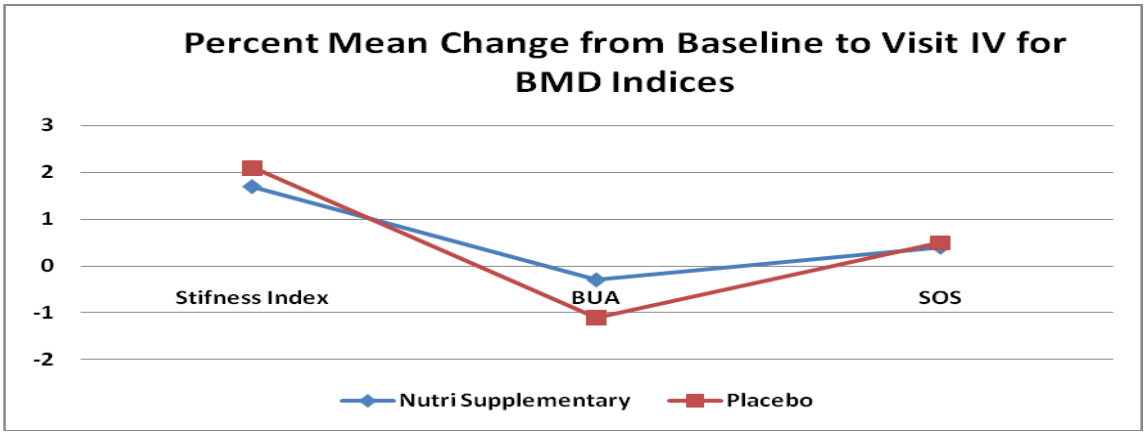

Fig 13: Percent Mean Changes from Baseline to Visit IV for BMD Indices Were clearly depicted graphically.

DISCUSSION:

A well planned study with good-quality research studies on the efficacy of natural health products for OA is limited. The recommendations are for OA clinical trials to be designed as parallel studies that are single, randomized, double-blind, and placebo-controlled, though crossover studies are also considered to be appropriate.The aim of the present study was to assess the efficacy and safety of Nutricharge BJ for bone health in elderly population. Bone health is a multi-factorial musculoskeletal issue (1). A combination of nutrients and natural ingredients containing potent concentrations of amino acids, anti-oxidants, vitamins and minerals will serve as Bone health promoters. The active ingredients contained in the product were chosen to enhance the bone health in elderly population. Recent scientific research and clinical testing supports their health benefits.

Bone Mineral Density (BMD) and bone metabolism are affected by genetic, endocrine, mechanical, and nutritional factors, with extensive interactions between the different factors (2, 3). Study subjects from both treatment and placebo groups were evaluated at the beginning and at the end of study period showed potentiality of Nutricharge BJ using SF-MPQ2, Pain Visual Analogue Scale, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Pain Scale and PT Assessment questionnaire of pain scores.

The Pain Scale function scores after and before periods of follow-up showed significant difference in reduction of pain (87.3%) between the two groups followed by WOMAC (73.7%) and SFMPQ2 which is to the tune of 57.5%.It could be that the Nutricharge BJ supplements provided a meaningful clinical benefit to arthritis and joint pain. However, there was clinically significant effect onknee symptoms due to theprescribed usage of nutritional supplement. The trial also analyzed a subgroup of people with moderate to severe joint pains and found that improved pain and joint function better than placebo treatment for this subgroup.

CONCLUSION:

The prevalence of arthritis is increasing and this places a globally major burden on individuals; health systems, and social care systems. The most common arthritis condition is a major cause of impaired mobility and disability for the ageing populations. While there are several drugs available on the market that mitigate pain and improve function, there are no drugs that can cure, reverse or halt disease progression. There are a number of drugs in the pipeline under development and several studies are also evaluating alternative therapies. There are, however, several drugs on the market whose clinical effectiveness and long-term safety still need to be determined. In conclusion, the present investigation suggests that Nutricharge BJ is able to effectively increase the Stiffness Index thereby increasing the BMD and bone health in elderly people both in male and female population. It is effective in decreasing pain which was evidently proved by the pain scores reported using different pain scale functions. The effective usage of Nutricharge BJ will enhance bone health in elderly population and also useful in the management of the knee joint pain.

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